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Human dignity in a comparative perspective: embryo protection regimes in Italy and Germany

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ABSTRACT


In this article, we explore the extent to which a dignitarian ethic can effectively shape regulatory policy in the area of biomedical practices which involve the use of human embryos. Drawing on the comparison of how Italy and Germany deliberated the ways in which assisted reproductive technologies and human embryo stem cell research should be governed, we explore the conditions that affect the potential of a dignitarian ethic to effectively shape countries' policy on these issues. We argue that two factors substantially affect its success. The first factor is the position of dignitarianism in the country's bioethical landscape, that is, whether it is the dominant bioethical perspective or competes with other perspectives for regulatory relevance. The second factor is the willingness of the regulators to strike compromises with their opponents if dignitarianism is not the main bioethical perspective and competes with other ethical perspectives for regulatory relevance. Building on our analysis, we conclude by drawing three general patterns of the relationships between countries' bioethical configurations and their regulatory policy.

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1. Introduction

Advances in human fertilisation and embryology have brought immense opportunities for medicine and human health. Technologies such as *in vitro* fertilisation (IVF), preimplantation genetic diagnosis (PGD) and human embryonic stem cell (hESC) research have contributed to managing serious health conditions and their further development is now widely associated with improved health.

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However, such ‘promised futures’¹ of improved health have not been the only vision of what these biomedical advances may bring. Both in philosophical and ethical debates and in more down-to-earth political discussions, criticism has been mounted that these technologies might lead to the violation and erosion of human dignity.² One of the criticisms that ‘dignitarianism’, as this position has been called,³ raises with respect to these technologies is that they involve the use of human embryos. Regardless of how human embryos are regarded, either as full-fledged human persons or as just one of the stages in the development of human life, their use for medical or scientific purposes is nevertheless seen as problematic because embryos due to their ‘humanity’ deserve respect and therefore cannot be treated as objects of scientific or biomedical research. Hence, the requirement to protect human dignity can imply the prohibition of commodification, instrumentalisation and commercialisation of human life. It thus derives from the philosophy of Kant, according to whom no human life can be used merely as a means to an end but only as an end in itself.⁴ Dignitarianism can also include the principle of ‘sanctity of life’ which has religious roots.⁵ Sanctity of life implies that the dignity of human life entails its inviolability and sacredness and therefore requires respect for every human life, including patients in a ‘vegetative state’ and unborn life.⁶ In the discussion on whether a relevant technology violates human dignity, the appeal to dignity often acts as a ‘conversation stopper’.⁷ All the possible therapeutic benefits that embryo use in medical treatment and scientific research might offer are regarded as irrelevant if such technological and scientific practices violate human dignity.

However, the extent to which the principle of human dignity can effectively shape regulatory policy on controversial biomedical issues is in need of exploration. Specifically, human dignity as described above constitutes the basis of only one and the most restrictive and disempowering ethic out of three strands of bioethical reasoning in the so-called ‘bioethical

¹Sarah Franklin and Margareth Lock, ‘Animation and Cessation: The Remaking of Life and Death’ in Sarah Franklin and Margareth Lock (eds), *Remaking Life and Death: Towards an Anthropology of the Biosciences* (SAR Press, 2003).

²Leon Kass, *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics* (Encounter Books, 2002); Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (Farrar, Straus & Giroux, 2002).

³Roger Brownsword, ‘Ethical Pluralism and the Regulation of Modern Biotechnology’ in Francesco Francioni (ed), *Biotechnologies and International Human Rights* (Hart Publishing, 2007) 45–70.

⁴Timothy Caulfield and Roger Brownsword, ‘Human Dignity: A Guide to Policy Making in the Biotechnology Era?’ (2006) 7 *Nature Reviews Genetics* 72.

⁵This connection between human dignity and sanctity of life was most clearly expressed by John Paul II in the encyclical *Evangelium Vitae*, according to which ‘the Gospel of the dignity of the person and the Gospel of life are a single and indivisible Gospel’: John Paul II, *Evangelium Vitae* (1995) <http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html>. This and all websites accessed 9 December 2016.

⁶Doris Schroeder, ‘Dignity: One, Two, Three, Four, Five, Still Counting’ (2010) 19 *Cambridge Quarterly of Healthcare Ethics* 118.

⁷Kurt Bayertz (ed), *Sanctity of Life and Human Dignity* (Springer Netherlands, 1996).

triangle’.⁸ Besides dignitarianism, the bioethical triangle includes liberal, emancipatory human rights ethics and pragmatic, utilitarian ethics. The problem hence emerges when these three bioethical perspectives start competing for regulatory relevance, thus urging policymakers to determine which of the three should shape policy and whether dignitarianism has some particular importance that could trump the other two ethics.

Furthermore, and to complicate things further, human dignity constitutes the basis of not only dignitarianism, but also of the human rights perspective.⁹ These two ethical perspectives build on two different versions of human dignity. Dignitarianism builds upon the restrictive version of dignity, or ‘dignity as constraint’. As stated above, it is rooted in religious beliefs or it is based on Kantian philosophy. Therefore, this principle entails that technologies such as human therapeutic and reproductive cloning, sex selection, tissue-typing and PGD may erode human dignity because they instrumentalise, commodify and destroy human life. Instead, the human rights perspective builds upon a liberal version of human dignity, or ‘dignity as empowerment’, which can be defined as autonomy and self-determination. This perspective does not treat new biomedical technologies as necessarily problematic and conditions their legitimacy upon the need to obtain the informed consent of the concerned patients.

The fact that human dignity underlies both bioethical perspectives, dignitarianism and the human rights approach, further aggravates the problem for policymakers. For example, this problem is particularly pertinent when the interpretation of laws that build on human dignity is required. In the absence of a definition of human dignity that settles the matter, it is not clear whether the legislator implied human dignity as constraint or human dignity as empowerment. Therefore, even if the intent to protect human dignity might be uncontested by the parties to the debate, competition between several bioethical perspectives might still take place due to the intention of the promoters of different bioethical perspectives to interpret human dignity in a more liberal or more restrictive way.

Taking the aforementioned problems into account, we explore how, when and under which circumstances the appeal to human dignity in public debates around new technological and scientific practices becomes problematic. To do this, we compare how Italy and Germany discussed and adopted policies on assisted reproductive technologies (ART) and hESC. Italy and Germany are commonly used as examples of countries whose restrictive policies on ART and embryo research have been influenced by the presence of strong dignitarian traditions. However, despite this apparent similarity, the two countries differ in terms of the timing of the adopted laws and their durability. The

⁸Brownsword (n 3).

⁹Ibid.

German Embryo Protection Act (*Embryonenschutzgesetz*, hereafter EPA) was passed in 1990 after five years of deliberation of its text. It has been in force since its inception and has since only been modified and complemented to regulate new technologies, including PGD and hESC. By contrast, the Italian Parliament deliberated the law on medically assisted reproduction (*Legge sulla procreazione medicalmente assistita*, hereafter Law on MAR) for 20 years after the first bills on IVF had been drafted, and adopted it only in 2004. However, within five years, almost all its restrictive provisions were repealed by the Constitutional Court as unconstitutional. Thus, while the dignitarian tradition led to the adoption of a workable and enduring law in Germany, the Italian law, similarly influenced by the value of human dignity, was subject to a lengthy discussion, only to see many of its articles invalidated as unconstitutional in a short period. Summarised bluntly, in Germany, the dignitarian tradition led to an enduring and workable EPA, while in Italy it led to a controversial and, ultimately, unconstitutional Law on MAR.

The main argument of our article is that in both countries human dignity as constraint played a key role in the political debate around the new ART and hESC research, mainly because these were framed as a potential assault on human dignity. Yet, the two countries differed in terms of their success to build their policies regarding ART and hESC research upon the principle of human dignity. We suggest that two factors were responsible for this difference. The first factor was whether dignitarianism was the dominant bioethical perspective in the relevant country. The second factor was the degree to which the regulators were willing to strike compromises with their opponents if dignitarianism was not the dominant bioethical perspective or was competing with other bioethical perspectives for regulatory relevance.

While the focus of this paper is on human dignity and the possible difficulties in implementing it through policy, we argue that its conclusions are also indicative of general patterns of the relationships between particular bioethical configurations and regulatory outcomes. Indeed, much research has shown the connection between countries' bioethical landscapes and the eventual regulatory outcomes of the debate on new biomedical technologies.¹⁰ This article contributes to this research in two ways. First, it illustrates the importance of not only the presence of dominant bioethical perspectives, but also the ability and willingness of their supporters to strike compromises and to form coalitions with opponents. Second, it provides a more detailed account of how exactly such bioethical configurations translate into policies. In the conclusion, we will draw three broad patterns of how exactly bioethical configurations may shape regulatory policy.

¹⁰Tanja Krones and Gerd Richter, 'Preimplantation Genetic Diagnosis (PGD): European Perspectives and the German Situation' (2004) 29 *The Journal of Medicine and Philosophy* 623; Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, 2005); Stefan Sperling, *Reasons of Conscience* (University of Chicago Press, 2013).

We shall proceed as follows. In Section 2, we will describe the debate around the Italian Law on MAR, both its discussion in Parliament and its invalidation by the Constitutional Court. In Section 3, we shall explore how the German government discussed the EPA and how it amended it to account for new technologies such as PGD and hESC. In Section 4, we will analyse and compare the two countries and conclude why human dignity succeeded in materialising in the German EPA and Stem Cell Act (*Stammzellgesetz*, hereafter SCA) and failed to do so in the Italian Law on MAR. Finally, we will derive three broad patterns in the relationship between countries' bioethical landscape and their regulatory policy.

2. Italy, sanctity of life and the debate on the Law on MAR

Italy opened its laboratories to ART in 1984 when Italian doctors performed their first IVF procedures. At the same time, the Italian State made its first attempts to regulate the provision of ART services on its territory. As ART were still new technologies, raising ethical, legal and safety concerns, the then Minister of Health Costante Degan instituted an interdisciplinary commission entrusted with exploring various aspects of ART and issuing reports that could subsequently be used as the basis for a law on ART. The commission included doctors, scientists, philosophers, and legal scholars and was presided over by judge Fernando Santosuoso.

The reports produced by the Santosuoso Commission had a rather restrictive approach towards ART and embryo research, employing a clearly deontological reasoning.¹¹ IVF embryos were defined as 'subjects' whose primary legal entitlement was the right to life. Therefore, the reports prohibited embryo selection and the creation of embryos for other purposes than the initiation of pregnancy, such as scientific research. Finally, they also suggested that only as many embryos should be created as would be implanted into the woman, in order to prevent the creation of supernumerary embryos. In case the implantation of embryos would fail, the non-implanted embryos could be cryopreserved for later implantation into the same or another woman. In the latter case, equating embryos with born children, it prescribed that the implantation should be performed under the supervision of the Juvenile Court, similarly to the adoption procedure.

The reports of the Santosuoso Commission were not implemented by the Minister of Health. As Flamigni and Mori ironically suggest, he found them too liberal.¹² Instead, two months prior to their publication, he issued a ministerial circular named 'Limits and conditions of legitimacy of services for

¹¹Commissione Santosuoso, 'Proposte di disciplina della nuova genetica umana' (1986) 2 *Giurisprudenza Italiana* 33.

¹²Carlo Flamigni and Maurizio Mori, *La Legge Sulla Procreazione Medicalmente Assistita* (Net, 2005).

artificial insemination in the domain of the National Health Service'.¹³ The Circular aimed at regulating artificial insemination alone, but also contained several provisions regulating the procedures regarding embryos. Specifically, the Circular entirely prohibited embryo cryopreservation and only allowed the creation of embryos that were required for implantation. However, the Circular applied to public centres only, thus leaving private centres beyond its regulatory reach. The adoption of the Circular thus addressed the need for regulation; however, due to its limited scope of application, it satisfied this need only partially.

2.1. Sanctity of life, the Catholic/secular cleavage and underregulation

Simultaneously with the governmental attempts to regulate ART and embryo research, Parliament also wished to place these under state control. From the very beginning of the debate, a substantial number of bills, mainly drafted by the members of Christian Democracy (*Democrazia Christiana*, hereafter DC), had been presented to Parliament that called for the prohibition of any type of clinical and scientific manipulation of human embryos from the moment of fertilisation, including the creation of supernumerary embryos, their cryopreservation, testing, selection based on morphological or genetic conditions, scientific research and destruction. This prohibition was warranted because, according to the bills' drafters, embryos from the moment of fertilisation were already full-fledged human persons. The belonging of the '*nascituri*' ('those to be born'), as embryos have been interchangeably called, to the moral community of people meant that they possessed human dignity and that their life was therefore inviolable. For example, the bill presented by Mino Martinazzoli, president of DC, and Carlo Casini, president of the Italian pro-life association Movement for Life (*Movimento per la Vita*, hereafter MpV) and a DC member (Martinazzoli bill), which was to be resubmitted many times throughout the debate, explicitly stated that there exist no interests that could outweigh the importance of preserving human life, including the life of the embryo.¹⁴

Another purpose of these bills, including the Martinazzoli bill, was to explicitly recognise IVF embryos as legal subjects and holders of the right to life. According to the Italian law on abortion, foetuses are neither 'persons' nor legal subjects enjoying the right to life,¹⁵ but they do 'enjoy the inalienable rights of human beings' and are thus protected by general art 2 of the

¹³Circolare 1 marzo 1985, n 100/119657/32.2.14, *Limiti e condizioni di legittimità dei servizi per l'inseminazione artificiale nell'ambito del Servizio Sanitario Aziendale*.

¹⁴Camera dei Deputati, *Proposta di legge (Norme a tutela dell'embrione umano)* n 3486. X Legislatura, 22 dicembre 1988: <http://legislature.camera.it/_dati/leg10/lavori/stampati/pdf/34860001.pdf>

¹⁵Corte cost 18 febbraio 1975 n 27, in *Giur cost*, 1975, p 117 ss.

Italian Constitution.¹⁶ Unsatisfied with the partiality of legal protection of embryos, the Martinazzoli bill stated that its main goal was ‘to extend the protection of the right to health and to physical integrity onto the initial phase of human existence’¹⁷ and thereby to recognise human embryos as a subject of rights, particularly of the right to life. Along with the prohibition against clinical and scientific manipulation of the embryo, the recognition of IVF embryos as legal subjects, whose primary right was the right to life, was regarded as the best means for ensuring their protection by the State.¹⁸

This framing of embryos as human persons and legal subjects was attacked by more liberal politicians, largely belonging to the Italian Communist Party (*Partito Comunista Italiano*, hereafter PCI). One of the main discursive strategies they employed was to oppose religion and the state. They stressed that the issue of an embryo’s moral status was a personal and subjective value, influenced by one’s religious views, and therefore could not serve as the basis for secular laws. Instead of focusing on the need to protect embryos against manipulation, they emphasised other risks that ART raise, especially if left unregulated, and thereby sought to reproblematised ART. Specifically, they stressed the need to prevent the commercialisation of reproductive technologies, ‘exploitation’ of patients, infliction of harm on women and new-borns, medical malpractice and a number of controversial practices such as eugenics and surrogacy.¹⁹

Thus, from the very beginning, the deliberative space on ART and embryo research in Italy was characterised by two ways in which ART and embryo research were problematised. These problematisations built on two different understandings of what should be the basis for laws on ART and embryo research, that is, the protection of embryos’ dignity and life or, in contrast, the prevention of medical malpractice and the protection of patients’ health. The presence of these two different problematisations was an expression of a deep secular/religious cleavage running throughout both Italian politics and society alike. In the political debates, these problematisations were advanced and supported by two groups of politicians. DC members supported full embryo protection and an absolute right to life of the embryo. In their struggle for implementing this principle through laws, they were supported by the Catholic Church, which retained its role of an influential political actor and opinion-maker despite the secularisation of Italian society.²⁰

¹⁶Art 2 of the Italian Constitution: ‘The Republic recognizes and guarantees the inviolable rights of the person, both as an individual and in the social groups where human personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled.’

¹⁷Camera dei Deputati (n 14).

¹⁸Camera dei Deputati. *Assamblea, Resoconto stenografico*. XIII Legislatura, 395 Seduta, 20 luglio 1998: <http://leg13.camera.it/_dati/leg13/lavori/stenografici/sed395/s030r.htm>

¹⁹Camera dei Deputati, *Proposta di legge (Norme sulla inseminazione artificiale e sulla fecondazione in vitro)*, n 1304. IX Legislatura, 17 aprile 1985: <<https://www.senato.it/service/PDF/PDFServer/DF/277857.pdf>>

²⁰Franco Garelli, ‘La rilevanza concreta e pubblica del cattolicesimo italiano’ (2005) 5 *Il Mulino* 823.

Its influence on Italian politics would be further reinforced at the beginning of the 1990s, when the corruption scandals led to the dissolution of the main political parties and emergence of smaller political parties, many of which would turn to Catholicism in search for their political identity.²¹ In contrast, PCI members rejected that human embryos necessarily had human dignity and instead emphasised the need to protect women's health. This secular/Catholic cleavage of the Italian party system was to be the main principle structuring the debate around embryo use in medical and scientific practices in Italy. Furthermore, running through the entire Italian society alike, it split both lay citizens and the Italian medical and scientific community on the issue of the 'moral and legal status of the embryo' and thus on how ART and embryo research should be regulated.²²

One of the main consequences of this cleavage was a difficulty in achieving consensus on how to regulate ART and embryo research. This led to the incapacity of the Italian Parliament to come up with any law on ART and embryo research for 20 years. As a result, the Circular remained the only instrument regulating the provision of ART services and embryo research in the country. However, because it applied to public fertility clinics only, private centres remained outside its regulatory reach and instead were subject to self-regulatory governance.²³ The self-regulation of doctors practising ART in the private sector led to a rather liberal approach towards ART. Private Italian clinics engaged in practising a wide range of ART procedures, ranging from more widespread ones such as creating supernumerary embryos and embryo cryopreservation to more controversial ones such as surrogacy, egg donation, and the fertilisation of menopausal and single women. Due to this permissibility, sceptical observers defined Italy as a 'Procreative Far West' country.

As a result of this permissive approach towards ART, large numbers of embryos accumulated in Italian private clinics. This situation had a substantial impact on the approach of pro-life politicians towards ART and embryo protection. Embryos, besides being framed as full-fledged human persons and having an absolute right to life, started to be framed as weak, little and still unprotected little children whose life and health was at stake due to the 'deviant egoism of those who want to have a child at any cost'.²⁴ Women, instead, were regarded as the main subjects responsible for transgressing the established boundaries and putting at stake the interests of IVF embryos. In the discussion of the law's text in Parliament, this urged

²¹Alberto Melloni, 'Tre fasi nel rapporto fra Chiesa, episcopato e politica' (2006) 6 *Il Mulino* 1056.

²²Celina Ramjoué and Ulrich Klöti, 'ART Policy in Italy Explaining the Lack of Comprehensive Regulation' in Ivar Bleiklie and others (eds), *Comparative Biomedical Policy: Governing Assisted Reproductive Technologies* (Routledge, 2004).

²³Isabelle Engeli and Christine Rothmayr Allison, 'When Doctors Shape Policy: The Impact of Self-Regulation on Governing Human Biotechnology' (2016) 10 *Regulation & Governance* 248.

²⁴Senato della Repubblica, *Proposta di legge (Norme in materia di procreazione assistita)*, n 112. XIV Legislatura, 6 giugno 2001, 2: <<https://www.senato.it/service/PDF/PDFServer/DF/63552.pdf>>

pro-life politicians to emphasise even more strongly the need for an absolute protection of embryos' right to life even against the entitlements of prospective mothers to procreate and have their rights protected.²⁵

The debate around ART and embryo research in Italy was therefore taking place around a problem that interpretative policy analysis defines as 'wicked problems'. According to Fisher, 'wicked problems' are problems 'in which we not only don't know the solution but are not even sure what the problem is'.²⁶ Often, wicked problems can emerge in debates around moral and therefore frequently irreconcilable values. Italian society, split around the issue of the 'moral status of the embryo' and hence embryos' entitlements, was similarly engaged in discussing what exact problem ART and embryo research actually raised. Was it the problem of violating the sanctity of life or was it possible risks to citizens' health? The inability to reconcile views on the issue of the 'moral status of the embryo' led to the failure to adopt a law and to a *de facto* permissive regime.

2.2. The debate around the Bolognesi bill, sanctity of life and the regulation of fertility treatment

The discussion of the co-called Bolognesi bill provides a vivid illustration of what the idea to protect human dignity conceptualised as sanctity of life meant in practice. In 1998, largely due to the high-profile case of cloning the first mammalian animal Dolly the sheep, the government renewed its attempts to bring ART and embryo research under state control. It assigned the task of preparing the first draft of a unified bill to the Commission on Social Affairs of the Chamber of Deputies. The parliamentary coalition at that moment was centrist-left, which suggested that a more permissive bill on ART might be adopted. Furthermore, the president of the Commission, Marida Bolognesi, herself a member of the Italian social-democratic political party Democrats of the Left (*Democratici di Sinistra – L'Ulivo*), was known for her feminist and rather liberal views on matters related to ART and abortion.²⁷ However, as a result of the corruption scandals of the beginning of the 1990s, the dissolution of the main DC and PCI, and the emergence of a large number of smaller parties, political parties were no longer representative of either religious or secular views. Instead, the latter were dispersed across the entire political spectrum. Therefore, Marida Bolognesi, attempting to attract the voices of Catholic members of the party, approved a compromise text of the 'Bolognesi bill'. It allowed a doctor to create a maximum of four embryos in one IVF cycle, transfer as many embryos as was deemed

²⁵Ibid.

²⁶Frank Fischer, *Citizens, Experts, and the Environment* (Duke University Press, 2000) 128.

²⁷Chiara Valentini, *La Fecondazione Proibita* (Feltrinelli, 2004).

appropriate to initiate pregnancy, and cryopreserve the remainder; however, the remaining embryos must be transferred into the same woman in the following cycles. The bill also prohibited embryo research. Thus, it did allow some form of embryo manipulation such as the creation of supernumerary embryos and cryopreservation; yet, responding to the voices of the Catholic members of the party and to their moral reservations about creating supernumerary embryos, it limited the number of producible embryos to four and prohibited embryo research.

However, absolutist voices precluded adoption of the law. Almost immediately after the bill was passed to the Chamber of Deputies, it was amended by including the embryo in the list of subjects whose rights the future law had to protect. In addition, to ensure absolute protection of embryos' right to life, the amended bill prohibited embryo cryopreservation and selection, and mandated the creation of a maximum of three embryos during one IVF cycle, all of which, even those holding pathologies, had to be implanted into the woman's uterus. Furthermore, pro-life politicians stressed the need to prohibit both women and men from withdrawing consent after the fertilisation of the patient's eggs. The main reason for this amendment was to protect embryos' right to life from the moment of fertilisation till implantation, if the couple were to change their mind regarding the implantation of embryos.²⁸ Finally, pro-life politicians proposed to prohibit PGD. According to them, PGD would involve the selection of human embryos based on their genetic profile, or in other words, a 'eugenic practice'.²⁹ Furthermore, PGD did not simply treat different forms of life differently, but presupposed the discarding and elimination of embryos that bore pathological genes. PGD thus represented a double offence against human life: not only did it imply selection, but it also built upon 'the affirmation that diseases can be treated by killing the sick'.³⁰

Liberal politicians criticised these restrictions as not paying enough attention to the interests of adult Italian citizens involved in ART, especially to those of women, as women's bodies were the main object of treatment. They argued that the prohibition on creating more than three embryos would force the doctor to perform repeated ovarian stimulations of the woman, thus raising the risks of such health conditions as ovarian hyperstimulation syndrome (OHSS) and ovarian cancer. They criticised the provision prohibiting withdrawal of consent after egg fertilisation, as it would violate the principle of informed consent and amount to forced treatment of women.

²⁸Senato della Repubblica, Assamblea, *Resoconto stenografico*. XIII Legislatura, 852 Seduta (pom), 7 giugno 2000: <<http://www.senato.it/service/PDF/PDFServer/BGT/6064.pdf>>

²⁹Camera dei Deputati, Assamblea, *Resoconto stenografico*. XIV Legislatura, 421 Seduta, 10 febbraio 2004: <http://leg14.camera.it/_dati/leg14/lavori/stenografici/sed421/00470b04.htm>

³⁰Senato della Repubblica, Assamblea, *Resoconto stenografico*. XIV Legislatura, 499 Seduta (ant), 03 dicembre 2003: <http://www.senato.it/japp/bgt/showdoc/frame.jsp?tipodoc=Resaula&leg=14&id=00114374&part=doc_dc-ressten_rs-ddltit_rddddd1514eapa&parse=no&stampa=si&toc=no>

Furthermore, the prohibition of PGD would cause ‘true family tragedies’³¹ and require ‘from couples a heroism that the law cannot require’,³² as it would force couples to raise children with severe genetic pathologies or force women to perform abortion, a much more harmful procedure than PGD. Yet, all attempts by liberal politicians to reduce the restrictiveness would fall short in face of the reluctance of pro-life politicians to negotiate the value of embryo life with other values, including health of the mother.

2.3. Embryo and hESC research

The regulation of embryo and hESC research in Italy was another hotly contested topic. During the discussion of the Bolognesi bill, how embryo research should be regulated in Italy was a secondary issue, yielding primacy to the issue of fertility treatment. It got prominence only in 2000, when the British government decided to amend the Human Fertilisation and Embryology Act to allow research on stem cells. This led to a full-blown controversy on whether hESC research should be allowed in Italy.

First, a brief explanation of what embryonic stem cells are is warranted. Stem cells were isolated from an embryo and grown for the first time in 1998. They are taken from an embryo at the blastocyst stage, normally five days after fertilisation of an egg cell. At this stage the embryo cells are pluripotent (capable of growing into many but not all types of cells) and therefore cannot become embryos. This makes them a useful and promising tool for curing diseases, such as Parkinson’s disease. However, because the extraction of stem cells from embryos involves their destruction, it raises similar concerns as research on embryos.

Similar to the discussion of fertility treatment, the debate around the legitimacy of performing hESC research was first problematised as an assault on human dignity and a violation of the right to life. The views of discussants, who included both politicians and scientists, split along the secular/Catholic cleavage. The proponents of hESC emphasised the therapeutic benefits of hESC and the potential of such research to provide new cures for presently untreatable diseases. In contrast, the opponents claimed that hESC violates human dignity and embryos’ right to life. Similarly to the debate on fertility treatment, the second group of politicians was backed by the Vatican, which used the debate on stem cells to further advance its goals on the ‘re-Christianisation’ of Italy.³³ Furthermore, in addition to employing

³¹Ibid.

³²Senato della Repubblica, *Assamblea, Resoconto sommario*. XIV Legislatura, 504 Seduta (ant), 10 dicembre 2003. <http://www.senato.it/japp/bgt/showdoc/frame.jsp?tipodoc=Resaula&leg=14&id=00090770&part=doc_dc&parse=no>

³³Alberta Giorgi, ‘Ahab and the White Whale: The Contemporary Debate around the Forms of Catholic Political Commitment in Italy’ (2013) 20 *Democratization* 895.

ethical arguments in the debate, they also argued that hESC research gives worse results than research on adult stem cells. As Beltrame argued, by engaging in the discussion about therapeutic benefits of different types of research, Catholic politicians and scientists attempted to shift the debate from the ethical to the epistemic domain and thus to problematise the debate on hESC further by calling into question the therapeutic efficiency of hESC research.³⁴ However, such reproblematisation was indeed anything but uncontroversial; instead of removing ethics from the debate about hESC, such reproblematisation indirectly asserted a moral status of the embryo as a full-fledged human being. Instead, the polarisation was reinforced as it was no longer only about the moral status of the embryo, but also about scientific evidence and knowledge.

In 2000, the then Minister of Health Umberto Veronesi instituted an ad hoc commission, including 25 members and presided over by the Nobel Prize winner oncologist Renato Dulbecco, in order to explore the ethical implications of hESC research. The final report was published in 2003.³⁵ The members of the commission agreed that hESC provides significant benefits for medicine. However, they split on the issue of the ethics of using hESC for medical purposes. While the majority of the Commission's members supported the use of surplus embryos for deriving hESC, seven Catholic members opposed the use of all embryos, even of surplus ones. They argued that the embryo was a full-fledged human person, whose right to life and human dignity had to be protected, and no other benefits, including medical ones, could outweigh the value of its life.

One of these Catholic members was Girolamo Sirchia, an outspoken proponent of research on adult stem cells. In 2001, when Italy had its parliamentary elections and the Berlusconi-led coalition won, Sirchia was appointed a new Minister of Health. After he took the post, Sirchia 'promised' to institute a new expert commission that would provide an 'alternative' expert report. Despite the fact that this alternative commission was not established, the reports of the Dulbecco Commission were not taken into account by the new Italian government and ended up in a drawer. Instead, immediately following his appointment, Sirchia issued a regulation on funding schemes of Italian science. The regulation did not include funding for hESC and covered only adult stem cells. Notwithstanding that no official regulation of hESC was produced, the governmental decision not to assign funds for hESC research was indicative of the then government's reluctance to find

³⁴Lorenzo Beltrame, 'Disputing the Boundary of Pluripotency: The Italian Public Debate on Amniotic Fluid-Derived Stem Cells' (2013) 32 *New Genetics and Society* 385; Lorenzo Beltrame 'The Therapeutic Promise of Pluripotency and Its Political Use in the Italian Stem Cell Debate' (2014) 23 *Science as Culture* 493.

³⁵Ministero della Sanità, *Relazione della Commissione di studio sull'utilizzo di cellule staminali per finalità terapeutiche*. XIII Legislatura, 28 dicembre 2000: <http://salute.aduc.it/staminali/documento/relazione+della+commissione+studio+sull+utilizzo_2082.php>

ethically ambiguous hESC research. The prohibition of conducting hESC research would be fully implemented with the enactment of the Law on MAR.

2.4. The adoption of the Law on MAR and the institutionalisation of sanctity of life

In the elections of 2001, central-right parties occupied the majority of seats in Parliament. After the restrictive text of the bill was approved by the Chamber of Deputies, the bill was in limbo awaiting discussion in the Senate. The Government appeared in no hurry, however. The situation changed with the intervention of the Vatican.³⁶ In February 2003, representatives of the Government met with the Vatican clergy on the occasion of the anniversary of the signing of the Lateran Pacts. The Pope expressed the Vatican's concerns with the Government policy such as its support of the war in Iraq and the implementation of discriminatory laws on immigration. He stressed that the Vatican could provide political backing if the law on assisted reproduction in its restrictive version would be approved as soon as possible.³⁷ After this meeting the position of the Government changed drastically. In December 2003, the Government obtained the approval of the Bill by the Senate. After the second approval of the Bill by the Chamber of Deputies, on 10 February 2004, it was passed as the Law on MAR.³⁸

In art 1, the Law recognised the human embryo as a right-holder, although it did not give a definition of the embryo. It allowed access to ART only to infertile couples if other methods of treating infertility proved unsuccessful. Further, in art 13, the Law forbade embryo experimentation, prescribed that clinical and experimental research must be performed only for the sake of the embryo itself, and forbade the creation of embryos for scientific and experimental research and eugenic embryo selection. Finally, in art 14 it prohibited the discarding and cryopreservation of embryos, and further prescribed that doctors must not 'create embryos in a number higher than the one strictly necessary for a single and simultaneous transfer, and in any case not more than three'. The only exception to the prohibition of embryo cryopreservation were serious health issues of the female patient, 'unforeseen at the moment of fertilisation', which allowed doctors to freeze embryos. However, after solving these health problems, the doctor was obliged to proceed with embryo implantation. In the same year as it was enacted, the Law's provisions were implemented into guidelines of the Ministry of Health introducing a new medical protocol for performing IVF both for public and private Italian clinics.

³⁶Valentini (n 27); Patrick Hanafin, *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy* (Ashgate, 2007).

³⁷Valentini (n 36) and Hanafin (n 36).

³⁸L 19 febbraio 2004 n 40, *Norme in materia di procreazione medicalmente assistita*.

Furthermore, three years later, another Circular was issued that specified what is meant exactly by ‘embryo’.³⁹ As stated before, art 1 of the Law on MAR did not specify this. As a result, doctors interpreted it as an entity that is formed with the fusion of the two pro-nucleuses. This means that from the moment the sperm meets the egg until the fusion of their pro-nucleuses, the entity was not an embryo, and therefore the restrictive provisions of the Law on MAR did not apply to it. Therefore, doctors could create a large number of oocytes, fertilise them and cryopreserve these ‘pre-embryos’, as they have been called by Italian doctors. In this way, they did not have to repeat the detrimental ovarian stimulation of the woman and jeopardise her health. In addition, this procedure gave comparable pregnancy rates as a regular IVF. Finally, they could perform polar body biopsy, an alternative to PGD, although it had a narrower scope of application and could detect only the mother’s genetic diseases. However, the Circular prohibited these practices. It built its decision on a common line of reasoning employed in the debate around the Law on MAR, according to which life should be protected from the beginning, hence with the penetration of the sperm into an egg and not with the fusion of the two (pro-)nucleuses. As will be seen later, in Germany both procedures were allowed, which made IVF significantly less restrictive there.

2.5. The challenge of the Law on MAR, abrogative referenda and litigation campaign

Predictably, the Law on MAR was not a legal instrument able to function as a compromise on the issue of IVF regulation. Instead, the debate shifted to other institutional settings.

2.5.1. Referendum

The enactment of the Law urged citizens who disagreed with the Law to organise an abrogative referendum against the Law.⁴⁰ Several questions were put to vote that concerned the liberalisation of fertility treatment and the possibility to perform scientific research on supernumerary embryos. This campaign was supported by many Italian researchers and scientific associations, such as the Luca Coscioni Association for the Freedom of Scientific Research. They claimed, first, that absolute embryo protection was a religious principle that could not be the basis for a law in a secular country. In

³⁹Manuela Perrotta, ‘Il Pre-Embrione (Non) È Uno Di Noi: Breve Storia Di Una Innovazione Inter-Organizzativa Tra Istituzioni, Comunità Professionali E Tecnologie’ (2011) 122 *Sociologia del Lavoro* 194.

⁴⁰Ingrid Metzler, ‘“Nationalizing Embryos”: The Politics of Human Embryonic Stem Cell Research in Italy’ (2007) 2 *BioSocieties* 413; Ingrid Metzler, ‘Between Church and State: Stem Cells, Embryos, and Citizens in Italian Politics’ in Sheila Jasanoff (ed), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (MIT Press, 2011) 105–24.

addition, they emphasised the principle of scientific freedom that was violated by prohibiting embryo research. The referendum failed, however, as the quorum was not met. The Catholic Church influenced this outcome. It organised a massive campaign against the referendum, calling Italian citizens to abstain from voting as 'life cannot be put to vote'. This strategy proved successful and only 25.7% of Italian citizens went to the polls. The threat posed to embryo's life by referenda and the possibility of repealing the newly enacted Law was foreclosed.

2.5.2. *Litigation*

In the same year, the debate around the Law shifted to a different – judicial – setting. Individual citizens, dissatisfied with the restrictive nature of the Law on MAR, continued to debate the law's granting of absolute protection to the IVF embryo's rights. They were supported by patient associations and fertility centres. The plaintiffs' main legal complaint was that the Law on MAR prohibits PGD and thereby violates women's right to health. Thus, the relationship of the mother and the embryo, whose opposing interests figured prominently during the debate on the Law on MAR and eventually underlay the Law's text, again became the topic of debate, this time in the courtrooms.

In 2009, only five years after the Law on MAR had been adopted, the Italian Constitutional Court acknowledged that the Law violates women's right to health.⁴¹ The question concerned the constitutionality of art 14 of the Law on MAR that obliged doctors to implant all created embryos simultaneously and prohibiting cryopreservation. The Constitutional Court concluded that this restriction could harm women's right to health, because it significantly limited the freedom of the treating doctor to apply individual treatment to every patient, that is, decide on the number of embryos to create and to implant. As a result, the Constitutional Court repealed the restriction that at most three embryos could be created and implanted simultaneously as well as the provision forbidding cryopreservation. Henceforth, embryos could be created in a 'scientifically justified number' to ensure good prospects of pregnancy and protect women's health.

Hence, the mechanism of litigation was used by those citizens and their collectives, including patients and medical associations, who disagreed with the value system upon which the Law on MAR was based, that is, the principle of the sanctity and inviolability of life of embryos. Furthermore, it attributed this value to a wide scope of embryonic entities, including fertilised eggs. Therefore, the Law on MAR excluded the voices of much of its constituency, such as patients, doctors, and scientists, whose activities and interests had been substantially curtailed. Those citizens who disagreed, believing that

⁴¹Corte cost, 1 aprile 2009 n 151: <<http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2009&numero=151>>

the law unreasonably prioritised the sanctity of embryo life over the mothers' right to health, used the mechanism of constitutional law to protect their entitlements. This mechanism was successful and the interests of the patients and doctors were recognised by the Constitutional Court, repealing the most restrictive provisions of the Law.⁴² In fact, such citizen resistance enabled a parallel and significantly more liberal rewriting of the Law.⁴³

2.6. ART and stem cells: back to underregulation

One consequence of the Constitutional Court's judgment was that the regulation of ART was again entrusted to doctors themselves. This resulted in a situation of significant legal uncertainty, which the Italian government made several attempts to address through regulation. First, the Minister of Health set up two expert commissions to update the Ministerial guidelines on ART by 2010. However, up till now, updates have not been published. Second, liberal parliamentarians introduced a number of bills to regulate the access of both fertile and infertile couples to PGD. Yet, none of them reached the parliamentary floor. Thus, the Italian ART sector, having existed without any state regulations for 20 years only to be suddenly overregulated when the Law on MAR was passed, returned to its pre-law state within a mere five years. Such issues as whether PGD was legitimate or not, which health conditions justified access to PGD as well as how, where and for how long supernumerary embryos should remain frozen did not have clear and precise legal answers. Some of these questions were addressed by the Constitutional Court when it repealed the prohibition for fertile couples to use PGD (art 4) and the prohibition of 'eugenic selection' (art 13) through its judgments in 2015.⁴⁴ Others, such as the destiny of cryopreserved embryos and the indication of the types of diseases that could be selected out via performing PGD, remained unregulated. Medical self-regulation again became the main instrument governing the provision of ART in general and PGD in particular in Italian fertility clinics. However, this mode of governance came into being not as a result of the State purposefully delegating power to the medical profession, but rather as a consequence of the State's failure to regulate ART and agree on how the wicked problem of the moral status of the embryo should be incorporated into laws, entailing legal uncertainty and insecurity, both for patients and the medical community.

⁴²Volha Parfenchyk, 'Redrawing the Boundary of Medical Expertise: Medically Assisted Reproduction and the Debate on Italian Bioconstitutionalism' (2016) 35 *New Genetics and Society* 329.

⁴³Patrick Hanafin, 'The Embryonic Sovereign and the Biological Citizen: The Biopolitics of Reproductive Rights' in Conor Gearty and Costas Douzinas (eds), *The Cambridge Companion to Human Rights Law* (Cambridge University Press, 2012).

⁴⁴Corte cost, 14 maggio 2015, n 96: <<http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2015&numero=96>>; Corte cost, 21 ottobre 2015, n 229: <<http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2015&numero=229>>

A rather similar thing happened with the import of hESC. To begin with, the failure to repeal the Law on MAR's restrictive provisions and the fact that the latter remained in force did not make embryonic stem cell research entirely impossible. Specifically, the Law on MAR said nothing with respect to the possibility of importing hESC from abroad. In the absence of a clear state position, scientists used the loophole in the Law and began importing hESC from abroad. In their permissive interpretation of the Law, they were backed by a substantial number of legal scholars.⁴⁵ However, the legitimacy of importing stem cells was not supported by many Italians, both lay citizens and scientists. For example, as Elena Cattaneo, a famous Italian researcher and supporter of stem cell research, stated in an interview, Italian scientists were willing to perform stem cell research and made frequent visits to her laboratory.⁴⁶ However, as they did not wish to be called 'unethical' scientists, in public they denied the fact that they performed such research. In addition, several organisations, mostly Catholic, insisted that the loophole in the Law should be interpreted restrictively, accusing the researchers who were importing stem cells of committing a criminal offence, which led to a further worsening of the societal debate with respect to stem cell research.

Thus, the lack of clear state regulations on stem cells entitled Italian scientists to autonomously decide whether they wished to perform research on hESC and, if so, how they wished to perform it. This freedom resembles the self-governance of Italian doctors before the adoption of the Law on MAR and after the invalidation of its provisions by the Constitutional Court in 2009. However, the lack of any regulations was far from a positive outcome. It led to various negative consequences, including the insecurity which Italian scientists experienced with respect to the legality of performing research on imported hESC.

2.7. Conclusion

ART and embryo research, including hESC research, were ultimately problematised in Italy as a potential assault on human dignity. Therefore, the Law on MAR that was eventually adopted represented a solution to the problem that ART and embryo research raised. This problematisation as well as the conceptualisation of human dignity itself as 'sanctity of life' emerged as a result of historical, cultural and political factors, among which the presence of the Catholic Church as an important political actor played a key role.

However, dignitarianism was not the main perspective in the Italian bioethics. The requirement to protect human dignity, or sanctity of life, of

⁴⁵Emilio Dolcini, 'Ricerca Su Cellule Staminali Embrionali Importate Dall'estero e Legge penale Italiana' (2006) 49 *Rivista Italiana di Diritto e Procedura Penale* 450.

⁴⁶Giuseppe Testa, Elena Cattaneo and Assunta Viteritti, 'The Italian Pathways of Stem Cells' (2013) 4 *Tecnoscienza* 145.

embryos was not supported by many lay people nor by decision-makers who adhered to more liberal views. In addition, the affinity of dignitarianism with the Catholic teaching raised objections on the part of the secular sections of Italian society, triggering even deeper disagreements among its supporters and opponents. Similarly, it entailed absolute and unrestricted protection of embryos' right to life even against the competing interests of the future mother. Embryos included all embryonic entities, including non-viable and sick ones, from the moment of penetration of the sperm cell into an egg. Such an encompassing scope of entities that had the right to life substantially restricted the treatment possibilities of Italian doctors, increased health risks for their patients and therefore further narrowed down the scope of those citizens supporting this ethical perspective and its implementation in law.

Despite this disagreement, the supporters of dignitarian ethics made little or no attempt to strike a compromise with their opponents. All attempts to find a middle-ground solution, such as the one undertaken by Marida Bolognesi, failed. As a result, this prevented the adoption of a law for 20 years. Italian patients were unprotected and clinics were stuffed with supernumerary embryos. Furthermore, even after the Law had been adopted, the debate did not stop but shifted to the courtrooms, and in no more than five years, the most restrictive provisions were repealed by the Italian Constitutional Court, hence reverting to a situation of *de facto* underregulation after a short period of overregulation.

3. Germany, non-instrumentalisation of life, and the debate on ART, hESC research and PGD

Similar to Italy, in 1984 the German Government instituted an interdisciplinary commission to study ethical aspects of ART. The Commission was presided over by the former German Constitutional Court president Ernst Benda, illustrating the importance of the commission's work. The resulting report was restrictive in nature, prohibiting the manipulation and instrumentalisation of embryos as a general rule.⁴⁷ According to it, embryos were entities worthy of protection because they constituted human life and therefore possessed human dignity, and the protection of the latter was the constitutional duty of the German State as envisaged by art 1 para 1 of the Basic Law. Specifically, it indicated that research on embryos might lead to such horrible scientific practices as Nazi experiments and eugenics and thereby violate the constitutional principle of human dignity. The report therefore prohibited germline engineering, embryo and sperm selection, surrogacy,

⁴⁷Benda Kommission, *In-vitro-Fertilisation, Genomanalyse und Genterapie: Bericht der gemeinsamen Arbeitsgruppe des Bundesministers für Forschung und Technologie und des Bundesministers der Justiz* (J Schweitzer Verlag, 1985).

the creation of embryos for scientific research, and the creation of more embryos than would ultimately be implanted into the woman. Unlike the Santosuoso Commission, it did not prescribe that embryos must be necessarily implanted, and if the woman for any reason changed her mind with respect to implantation, the embryos could be cryopreserved. Moreover, and importantly, the Commission allowed research on supernumerary embryos for ‘medical findings of great value’. By indicating that such research must be of ‘great value’, the Benda Commission attempted to make sure that embryos are not routinely used in laboratory experiments. However, the fact that it allowed their use for research meant that embryo protection was important, yet not absolute.

3.1. Parliamentary discussion, human dignity and adoption of the EPA

The report of the Benda Commission was not fully implemented when the German Government proposed its bill in 1989. Its aim was to establish boundaries for the use of IVF and genetic engineering when applied to humans, specifically by prohibiting any kind of manipulation during the initial stages of human life.⁴⁸ According to the Government, such a prohibition was required by the need to ensure the protection of human dignity (art 1 para 1 of the German Basic Law) and the right to life (art 2 para 2). Although the Government acknowledged the constitutional right to perform research (art 5), this right was limited by the need to protect human dignity.

To prevent the manipulation of human life at its initial stages and to thereby protect constitutional principles of human dignity, the Government included in the list of the forbidden procedures a rather wide range of techniques. They included the creation of embryos for purposes other than initiating pregnancy (in order to avoid the creation of embryos for research purposes), the use of embryos for scientific research, modifying germlines or fertilised eggs till the moment of fusion of the nucleuses, the fertilisation of more eggs than can be implanted in one cycle, cloning, the production of chimeras, choosing the gender of future children, the use of donor gametes, and surrogate motherhood. All these procedures were defined as crimes punishable by prison sentence or fines.

The government bill was also specific in defining what exactly it considered as ‘human life’ whose dignity the State had to protect. Specifically, according to art 8 the protection was accorded to embryonic entities from the moment of the fusion of the gametes’ nucleuses (i.e. zygotes), including totipotent cells (i.e. cells that can grow into all cell types) that could be derived from an

⁴⁸Deutscher Bundestag, Entwurf eines Gesetzes zum Schutz von Embryonen des Bundesregierung, 25 Oktober 1989, Drucksache 11/5460: <<http://dipbt.bundestag.de/doc/btd/11/054/1105460.pdf>>

embryo, because a totipotent cell has the potential to become an embryo. In addition, to be protected by the State embryos had to have the potential to develop and thus to be born.⁴⁹ Art 8 of the bill also stipulated that within the first 24 hours after fusion, when it is not certain whether an embryo will be able to develop, it is considered to be capable of development and therefore is also protected by the law. After these 24 hours, it can be already determined with full precision whether the embryo can develop. Thus, only embryos capable of developing and hence becoming individuals were protected by the law.

Finally, the bill sought to protect not only the dignity of embryos, but also the dignity of women. Thus, the bill criminalised the insertion of embryos into the woman against her will, as it would violate the principle of autonomy. Furthermore, it acknowledged the possibility that a woman might not want to have the embryos implanted, or could not have them implanted, for example, in case of illness. In such cases, the bill allowed embryos to be cryopreserved and even destroyed, if the woman did not want to proceed with implantation.⁵⁰

The German Senate, the Bundesrat, agreed that embryos should be protected according to the Basic Law and, similarly to the Government, based its judgment upon the State's duty to protect human dignity and human life. It also feared a *Dammbruch* – the breach of a floodgate: if research on embryos were allowed, then it would only proliferate as new forms of research goals would appear in the future. However, it asked itself whether embryos produced to initiate pregnancy, but are not implanted in the genetic mother and therefore not capable of developing into human beings, should be banned from research. These supernumerary embryos, according to the Bundesrat, are not protected by the law because they do not fit within the definition of embryos stipulated in art 8 of the law, as they do not have the capacity to develop. So too can it be questioned whether performing medical research on them would violate human dignity.

Responding to its own quandaries, the Bundesrat deemed a prohibition to perform research to be necessary, however. Performing research on supernumerary embryos could be dangerous because it could lead to a development that would ultimately be irreconcilable with the 'objective idea of human dignity'. Specifically, it could incite doctors to overproduce supernumerary embryos in order to satisfy the increasing demands of scientists to have more embryos at their disposal. Additionally, it could incite scientists to require the right to create embryos for research purposes if they do not have a sufficient number of supernumerary embryos. Therefore, the

⁴⁹Hans-Ludwig Günter, Jochen Taupitz and Peter Kaiser, *Embryonenschutzgesetz. Juristischer Kommentar mit medizinisch-naturwissenschaftlichen Grundlagen* (W Kohlhammer GmbH, 2014) 354.

⁵⁰Jochen Taupitz, 'The German Stem Cell Act' (2010) 11 *German Law Review* 1381.

Bundesrat, though questioning whether research on supernumerary embryos violates the human dignity of embryos, nevertheless advised the Government to prohibit research also on supernumerary embryos. This suggestion was accepted by the Government and incorporated in the bill before it was sent to Parliament.

During the parliamentary debates, the bill was modified to include a limitation of three embryos for implantation during one cycle in order to prevent the creation of supernumerary embryos. Three was chosen as a maximum because medicine at that time did not need more than three embryos to initiate pregnancy. Another amendment concerned the right to select sperm cells in order to avoid the transmission of a serious hereditary genetic disease from parents to children. The proposal of the Government did not contain this exception because sperm selection based on gender chromosomes was outlawed out of fear of eugenic practices.⁵¹ In the Bundestag the need to allow sperm selection was proposed by the Christian Democratic parties (CDU/CSU) in order to prevent the transmission of grave hereditary diseases to the children, e.g. Duchenne disease, or, if the woman would decide to abort a diseased foetus, to spare her the traumatic experience of abortion. After accepting the proposed amendments, Parliament voted in favour of the bill and on 1 January 1991, the Embryo Protection Act entered into force.

Hence, the debate around the EPA lasted only five years and was not particularly controversial. The constitutional value of human dignity and the shared agreement that human dignity also applied to unborn life, including embryos, played a key role in the rather speedy enactment of the EPA. As observed before, the EPA was rather widely supported by the political parties (apart from the Green Party [*die Grünen*]).⁵² This shared agreement emerged to a large extent due to the reluctance of the entire German society to repeat the mistakes of its Nazi past, which the inclusion of the principle of human dignity in the German Basic Law was meant to prevent.⁵³ This reluctance led to acknowledging that the instrumentalisation and commodification of all human life to which practices such as human embryo research, cloning or gender selection might lead must be prohibited.

3.2. The debate around hESC in Germany

A subsequent debate in Germany, on embryo research and hESC research, was provoked by the news about cloning Dolly the sheep in 1997 and was further intensified by announcements about the derivation of hESC in an

⁵¹Günther, Taupitz and Kaiser (n 49) 268.

⁵²Deutscher Bundestag, 'Beslu empfehlung und Bericht des Rechtsausschusses (6 Aussch u )', 8 Oktober 1990, Drucksache 11/8057 13: <<http://dipbt.bundestag.de/doc/btd/11/080/1108057.pdf>>

⁵³Sperling (n 10); Herbert Gottweis, 'Stem Cell Policies in the United States and in Germany' (2002) 30 *Policy Studies Journal* 444.

American clinic.⁵⁴ In Germany, the EPA did not clearly prohibit research on hESC, as hESC were pluripotent and not totipotent cells and therefore were not embryos. Although derivation of hESC involves the destruction of embryos, a practice prohibited by the EPA, German researchers could perform research on imported hESC and thus would not violate the general prohibition against embryo destruction. However, for some this would still involve the destruction of embryos abroad and therefore violate the spirit of the EPA. This legal loophole triggered an intense debate in German society about the legality of performing hESC research in Germany and how the EPA should be amended to accommodate new research possibilities.

The debate around hESC included many actors, which could be roughly divided into two groups. The first group, opposing hESC research, was rather heterogeneous, including Catholics, the Green Party and feminists.⁵⁵ Unlike Italy, where the Vatican imposed one main frame on embryo use in ART and hESC, hESC research was problematised in many ways in Germany. Thus, while Catholics framed it as a problem of embryo dignity and right to life, feminists emphasised socio-political consequences such as the use of women's bodies as raw material for research. On the other hand, medical and scientific associations such as the German Research Foundation (*Deutsche Forschungsgemeinschaft*, hereafter DFG) suggested that embryo research was promising because it could bring new cures.⁵⁶ DFG, specifically, appealed to a more liberal regulatory approach to hESC and even suggested changing the EPA. However, compared with opponents of hESC research, such liberal voices were in a clear minority.

However, in the end, the debate around hESC focused only on the moral status of the embryo. This result was provoked by an interview of a newly instated Minister of Cultural Affairs, Julian Nida-Rümelin, in *Tagesspiegel* in January 2001. He stated that embryos do not have self-esteem and therefore do not have human dignity, therefore the latter could not be violated. This led to public upheaval, for it was in direct contradiction with the publicly held opinion that embryos do have human dignity, as any other human being regardless of specific qualities. As a result, President Johannes Rau intervened with a speech and in sharp words defended human dignity and condemned the commodification of embryos. He stressed that the value of human dignity was a lesson learned from the crimes of Nazi-Germany.⁵⁷ In

⁵⁴James A Thomson and others, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145.

⁵⁵Svea L Herrmann, *Policy Debates on Reprogenetics: The Problematisation of New Research in Great Britain and Germany* (Campus Verlag, 2009) 169.

⁵⁶Deutsche Forschungsgemeinschaft, Empfehlungen der DFG zur Forschung mit menschlichen Stammzellen' (2001): <http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/download/empfehlungen_stammzellen_03_05_01.pdf>

⁵⁷Speech by President Rau at the special meeting of the German Bundestag on the occasion of the memorial day for the victims of national socialism (Rede bei der Sondersitzung des Deutschen Bundestages

another of his speeches, in May 2001, he claimed that medical research should never decide when human life should be protected, thereby pointing at the illegality of embryo research.⁵⁸

The problem of the moral status of the embryo also underlay the reports of the two commissions – the Enquiry Commission on Law and Ethics in Modern Medicine (*Recht und Ethik der modernen Medizin*) created by the Bundestag, and the National Ethical Council (*Deutscher Ethikrat*) created by Chancellor Gerhard Schröder – set up to explore ethical and legal problems related to hESC research.⁵⁹ Calls for a deliberate investigation of hESC were voiced when a German researcher, Oliver Brüstle, wishing to perform research on imported human embryonic stem cells, applied for funding at the DFG and the public debate turned into a political debate. Both commissions stated that the main ethical problem of hESC research was the destruction of embryos; since for many citizens, embryos had a right to life and dignity, their destruction might be ethically dubious as it would involve embryo instrumentalisation for the sake of performing scientific research. Yet, on the other hand, for other people embryos do not have dignity. They concluded that the problem of the embryo's moral status is thus unsolvable, as it is impossible to reconcile different ethical views. As a result, both commissions proposed to prohibit general research on embryos in Germany and the derivation of hESC in Germany. Yet, they differed with respect to importation of hESC; whereas the Enquire Commission was against any hESC research (26 to 12 votes),⁶⁰ the Ethical Council was in favour of hESC research by importing them from abroad (15 to 10 votes).⁶¹

The political debate on hESC finally led to a debate in Parliament. In January 2002, three motions (*Anträge*) on hESC research were discussed in Parliament. The first was from a politician of the social-democratic party (SPD). In line with the report of the Commission on Law and Ethics in Modern Medicine, it argued that human life starts at fertilisation with the fusion of two nucleuses, therefore it was the duty of the State to protect human life and human dignity of embryos against misuse and instrumentalisation. This requirement entailed the protection of embryos against third parties who would kill them to produce hESC for research and thus turning them into mere instruments. No distinction should be made between

aus Anlass des Gedenktages für die Opfer des Nationalsozialismus am 26 Januar 2001): <http://www.bundespraesident.de/SharedDocs/Reden/DE/Johannes-Rau/Reden/2001/01/20010126_Rede.html>

⁵⁸Berlin Speech president Rau ('Wird alles gut? Für einen Fortschritt nach menschlichem Maß'): <http://www.bundespraesident.de/SharedDocs/Reden/DE/Johannes-Rau/Reden/2001/05/20010518_Rede.html>

⁵⁹Sperling (n 10).

⁶⁰Deutscher Bundestag, Zweiter Zwischenbericht der Enquete-Kommission Recht und Ethik der modernen Medizin (2001) Drucksache 14/7546: <<http://dip21.bundestag.de/dip21/btd/14/075/1407546.pdf>>

⁶¹Nationaler Ethikrat, 'Zum Import menschlicher embryonaler Stammzellen' (Dezember 2011) 56: <<http://www.ethikrat.org/dateien/pdf/zum-import-menschlicher-embryonaler-stammzellen.pdf>>

embryos created inside and outside of Germany, therefore import of embryos and stem cells should also be prohibited.⁶² In addition, the motion sought to safeguard the dignity of women, to protect them from being turned into suppliers of raw materials for science, echoing others' arguments that were used in the public debate. Though the motion did acknowledge the constitutional right to freedom of research, it considered this right had to yield to the more important 'universal principle' of human dignity of human beings, independent of their stage of development and capabilities.⁶³ The second motion was from the liberal party (FDP).⁶⁴ It proposed the use of imported hESC derived from embryos created to initiate pregnancy. Being of a utilitarian nature, it suggested that hESC research should be endorsed because it would be beneficial for medical research and promote the public good.⁶⁵ The third motion, put forward by CDU/CSU member Horst Seehofer, former Green Minister Andrea Fischer and by the chairperson of the Law and Ethics of Modern Medicine Inquiry Commission and SPD member Margot von Renesse, also allowed the use of only imported hESC.⁶⁶ However, unlike the former, it included a substantial number of restrictions. This motion acknowledged that, on the one hand, hESC were not embryos and therefore their use was not in violation of the EPA and of the principle of human dignity. Therefore, the constitutional principle of freedom of research did not affect any constitutionally protected rights and principles. On the other hand, hESC research was ethically and constitutionally problematic because the derivation of hESC involved the destruction of embryos and therefore led to their instrumentalisation and destruction. Specifically, by approving the import of hESC, the law would violate the Basic Law if it would create a demand for new hESC and hence would lead to the destruction of embryos. To tackle this issue, its promoters suggested to allow the import of hESC created before the discussions of the motions in Parliament. To be fully consistent with the ethics enshrined in the EPA, they further limited hESC research to those that were derived from embryos created to induce pregnancy and not for research.

The debate around the three motions was highly emotional and lasted five hours.⁶⁷ Due to the ethical nature of the issue, the politicians were allowed to vote according to their conscience and not to their party ideology. The views

⁶²Deutscher Bundestag, Antrag Wodarg, Schutz der Menschenwürde angesichts der biomedizinischen Möglichkeiten –Kein Import embryonaler Stammzellen, 29 Januar 2002, Drucksache 14/8101, 2–3: <<http://dipbt.bundestag.de/doc/btd/14/081/1408101.pdf>>

⁶³Ibid, 4.

⁶⁴Deutscher Bundestag, Antrag Flach, Verantwortungsbewusste Forschung an embryonalen Stammzellen für eine ethisch hochwertige Medizin, 29 Januar 2002, Drucksache 14/8103: <<http://dipbt.bundestag.de/doc/btd/14/081/1408103.pdf>>

⁶⁵Jananoff (n 10) 197.

⁶⁶Deutscher Bundestag, Antrag Seehofer, Keine verbrauchende Embryonenforschung: Import humaner embryonaler Stammzellen grundsätzlich verbieten und nur unter engen Voraussetzungen Zulassen, 29 Januar 2002, Drucksache 14/8102, 2–3, <<http://dipbt.bundestag.de/doc/btd/14/081/1408102.pdf>>

split around the issue whether hESC would violate human dignity. The politicians opposing hESC research emphasised that hESC research would turn embryos into objects of research and thus violate their human dignity. They made no distinction between supernumerary and regular embryos, nor between German and imported embryos. Similarly, they feared that allowing hESC research would lead to a *Dammbruch*, in the future allowing cloning, more exceptions for the import of hESC or production of embryos for research.⁶⁸ In contrast, the politicians favouring hESC research stressed that by setting the cut-off date, the law would ensure that embryos ‘will not die for German research’.⁶⁹ As hESC themselves were not embryos, they were not protected by the Basic Law and therefore research on them would not violate human dignity.⁷⁰ They also put forward the promises of hESC research and downplayed the fear of a *Dammbruch*, pointing out the strict conditions for researchers to perform hESC research. At the end of the day, the third motion got the majority vote in Parliament, with 340 votes in favour and 265 against.⁷¹

Thus, as a general rule, the SCA outlawed hESC research, because such research would violate the principle of human dignity. Yet, it allowed importing hESC lines if they were created from supernumerary embryos before the cut-off date, which was set at 1 January 2002. This cut-off date was chosen to make sure that Germany would not stimulate the destruction of embryos anywhere in the world for German research purposes. Further, the SCA stipulated that to import hESC, scientists should first prove that the research could only be performed with hESC and not, for example, with animal stem cells. Lastly, the law contained a provision that obliged German researchers to submit proposals for hESC research to the Central Ethics Commission on Stem Cells for approval, before being allowed to actually import stem cells. This mechanism was intended to act as an additional safeguard against excesses or misuses.

Thus, the constitutional principle of human dignity significantly affected the outcome of the debate around hESC in Germany. Because it revolved around a principle that was widely shared, that embryos could not be used as objects and be destroyed for German research, the German Parliament managed to overcome the differences in views and quickly pass a law. Tellingly, none of the motions discussed in Parliament called for allowing the derivation of hESC from German embryos. Despite the attempts of

⁶⁷Herbert Gottweis, Brian Salter and Catherine Waldby, *The Global Politics of Human Embryonic Stem Cell Science: Regenerative Medicine in Transition* (Palgrave Macmillan, 2009).

⁶⁸Deutscher Bundestag, Stenographischer Bericht, 214. Sitzung, 30 Januar 2002, Plenarprotokoll 14/214 21209, 21213, 21214, 21218: <<http://dipbt.bundestag.de/doc/btp/14/14214.pdf>>

⁶⁹Sperling (n 10).

⁷⁰Deutscher Bundestag, Stenographischer Bericht, 214. Sitzung, 30 Januar 2002, Plenarprotokoll 14/214 21200, 21220: <<http://dipbt.bundestag.de/doc/btp/14/14214.pdf>>

⁷¹Thomas Banchoff, ‘Path Dependence and Value-Driven Issues: The Comparative Politics of Stem Cell Research’ (2005) 57 *World Politics* 220.

German scientists, represented by the DFG, to liberalise the policy on embryo research in Germany and oppose the German *Sondermoral* to the value of scientific research, the general consensus about the importance of protecting the constitutional principle of human dignity was deeply entrenched in German society. The absence of a deep cleavage like in Italy ensured a speedy passage of the SCA. By allowing the use of stem cell lines only from supernumerary embryos initially created for pregnancy and by setting the cut-off date, the German Parliament thus created an image of a responsible regulator, loyal to the fundamental ethical principles of German society.

Despite its consensual success, the SCA can be criticised for many reasons. It can be seen as hypocritical, protecting German supernumerary embryos from being used as material for stem cells while allowing the use of foreign embryos for this purpose. Interestingly, in 2008, six years after passing the SCA, Parliament amended it by choosing a new cut-off date for the use of embryos, that is, May 2007, which might again suggest hypocrisy of the German regulators. Furthermore, it can also be criticised for creating regulatory incoherence through combining in the same regulatory order two contradictory value systems.⁷² One of them builds upon the restrictive 'dignity as constraint' value, whereas the other has a more utilitarian nature, allowing German scientists to reap the benefits from research on embryos that in any case will be turned into hESC lines in countries with more liberal policies. Finally, a potential criticism is that by gradually increasing the number of such 'exceptions', the German regulator may in the long run betray the very idea of human dignity.⁷³ However, exactly this alleged 'hypocrisy' or 'incoherence' enabled the German regulator to pass the SCA and regulate hESC research on its territory. Unlike Italy, which came to a *de facto* liberal outcome on the regulation of hESC research as a result of a failure to compromise, Germany allowed the import of stem cells after a deliberate negotiation process and as a result of a willingness to account for different ethical views of its citizenry.

3.3. The debate on PGD in Germany

It was generally considered that the EPA, though not explicitly naming PGD, did not allow its use because the selection of embryos would violate the constitutional principle of human dignity upon which the EPA was built. However, since as early as the mid-1990s, German society had been deliberating the possibility to legitimise PGD. The main strategy for this was to attempt to reproblematising it. Specifically, according to the German Society

⁷²Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford University Press, 2008).

⁷³Kathrin Braun, 'From Ethical Exceptionalism to Ethical Exceptions: The Rule and Exception Model and the Changing Meaning of Ethics in German Bioregulation' (2016) *Developing World Bioethics* doi:10.1111/dewb.12103.

of Human Genetics (GfH), the prohibition of PGD was not consistent with parents' interests as it would force pregnant women to perform abortions.⁷⁴ A similar conclusion was reached by the ethics committee of a clinic in Lübeck, which was approached by two clinicians for advice on the issue of PGD. According to this committee, the EPA prohibited PGD. However, it wondered if such a prohibition would be ethical if it would force women to perform harmful abortions and thus create negative impacts upon their health.⁷⁵ Finally, in 2000 the German Medical Association (*Bundesärztekammer*, hereafter BÄK) published a discussion paper on PGD.⁷⁶ The BÄK framed the problem of PGD as a conflict between the embryo's right to life and the rights of parents, and concluded that because PGD was needed to protect the health of the future mother, it would not amount to eugenic practice and hence should be allowed.

In 2010, a crucial event happened affecting the legality of PGD in Germany. The Federal Court of Justice (*Bundesgerichtshof*, hereafter the BGH) had to decide upon a case of a German gynaecologist who performed PGD to prevent the passing of genetic disorders if these would lead to miscarriage, stillbirth or early death of the child. The gynaecologist performed three PGD operations and later turned himself in to the authorities. The BGH, however, acquitted him.⁷⁷ First, the BGH concluded that all the doctor's actions did not involve the misuse of embryos, strictly forbidden by the EPA. Instead, he performed PGD to make pregnancies possible, the only purpose that allowed the use of embryos according to the EPA. Second, it took into account that the EPA permitted sperm selection to avoid the creation of sick embryos. Drawing upon this analogy, it equated embryos with sperm cells and concluded that if sperm selection was allowed, then embryo selection should be allowed as well to prevent the passing of genetic disorders. Third, the German regulation on abortion permitted a termination if the foetus carried certain kinds of pathologies. Therefore, for the Court it was unreasonable to forbid PGD, given that abortion was significantly more intrusive and damaging than PGD. As a result, the Court decided that PGD was not a criminal offence under the EPA.

The ruling created legal uncertainty with respect to the legality of performing PGD in Germany and Parliament was quick to remove it. During the Parliamentary debate around PGD, three types of bills were presented. The first proposal, put forward by Green Party politician Katrin Göring-Eckardt, entirely prohibited PGD.⁷⁸ Its proponents argued that according to the

⁷⁴Herrmann (n 55).

⁷⁵*Ibid.*

⁷⁶Bundesärztekammer, Diskussionsentwurf zu einer Richtlinie zur Präimplantationsdiagnostik, in Sigrid Graumann (ed), *Die Genkontroverse. Grundpositionen* (Herder Spektrum, 2001) 157.

⁷⁷Bundesgerichtshof (BGH), Urteil vom 6 Juli 2010 – 5 StR 386/09.

⁷⁸Deutscher Bundestag, Entwurf eines Gesetzes zum Verbot der Präimplantationsdiagnostik, 11 April 2011, Drucksache 17/5450: <<http://dipbt.bundestag.de/dip21/btd/17/054/1705450.pdf>>

values of the Basic Law, every human being has the same dignity and the State cannot make decisions on which life is worthy of living and which is not, as it can lead to eugenic practices. This value system would be jeopardised if PGD were allowed. The second bill was put forward by SPD politician Peter René Rösper. It allowed PGD only to check the presence of serious genetic hereditary diseases in the embryo if these would lead to stillbirth, miscarriage or death of the baby in the first year of life and thus was similar to the BGH ruling.⁷⁹ The third proposal, proposed by FDP politician Ulrike Flach, was substantially more liberal. It allowed PGD to perform screening both to check the presence of genetic abnormalities if they would lead to miscarriage, stillbirth or the death of the baby in the first year and when the parents have a severe hereditary disease with a risk of at least 25% of passing it on to their offspring.⁸⁰

In 2011, only one year after the BGH ruling, Parliament voted for the third proposal, thus allowing PGD in both cases, that is, to check for genetic abnormalities in the baby if they would lead to miscarriage, stillbirth or death of the baby in the first year and when the parents have a severe hereditary disease. The amendment was incorporated into the EPA. According to the new art 3a of the EPA, PGD remained a crime. However, it was not unlawful to perform PGD to prevent passing a serious hereditary disease to the embryo, including if such a disease would lead to stillbirth or miscarriage. The amendment also instructed that the woman had to undergo counselling beforehand and stipulated the institution of ethics committees that had to provide oversight over PGD.

During the parliamentary debates in the Bundestag, the politicians opposing PGD argued that the selection of embryos for implantation violated human dignity as it constituted eugenic practice.⁸¹ Echoing the fear of Nazi eugenics, they stressed that the State should not decide which life would be worth living (*lebenswert*) and which life would not be (*lebensunwert*). In contrast, the politicians favouring PGD argued that allowing PGD would give German families a chance to avoid the psychological and social burden of raising children with severe genetic pathologies. They engaged in telling personal stories about people they knew whose lives were affected by similar experiences – for example, experiences from burying a baby of a few days old to the woman who lost six brothers due to the same genetic disease.⁸²

⁷⁹Deutscher Bundestag, Entwurf eines Gesetzes zur begrenzten Zulassung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG), 12 April 2011, Drucksache 17/5452: <<http://dipbt.bundestag.de/dip21/btd/17/054/1705452.pdf>>

⁸⁰Deutscher Bundestag, Entwurf eines Gesetzes zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG), 12 April 2011, Drucksache 17/5451: <<http://dipbt.bundestag.de/dip21/btd/17/054/1705451.pdf>>

⁸¹Deutscher Bundestag, Stenografischer Bericht, 105. Sitzung, 14 April 2011, Plenarprotokoll 17/105 11947, 11954, 11956, 11967: <<http://dipbt.bundestag.de/dip21/btp/17/17105.pdf>>

⁸²Ibid, 11946, 11955, 11972.

More importantly they stressed that it was not a question of a life *worth* living or not, but having the possibility for parents to have a baby *capable* of living (*lebensfähig*).

Interestingly, in their speeches, they made no reference to human dignity but chose a different technique. They stressed the obligation of the State to protect not (only) unborn life, but (also) adult German (female) citizens from heavy physical or mental burdens that might result from performing an abortion or raising a child with a severe genetic disease, allowing them to have a baby capable of living. Put differently, the main strategy of the German regulators in legitimising PGD was its reproblematisation. Instead of discussing how exactly PGD should be accommodated in order to be consistent with the German constitutional order and the principle of human dignity, the supporters of PGD ignored the discussion of the principle of human dignity altogether. Rather, they emphasised how the prohibition would affect German couples who would be forced to raise children with severe genetic pathologies or women who would be forced to perform an abortion. In other words, they emphasised that the German state was obliged to care not only about the dignity of embryos but also about the dignity of adult women. Hence, dignity as empowerment was brought to the fore in the debate on PGD, implying the need for a more liberal regulation of new biomedical practices.

And yet, the constitutional ideal of human dignity as constraint was not entirely absent. The amendment introduced in the EPA is reminiscent of how the German Constitutional Court allowed abortion.⁸³ As a general rule, abortion was considered a crime as performing it would violate human dignity. However, the State was obliged to take into account and protect not only the right to life of unborn foetuses, but also the life and health of women. Unlike human dignity, according to the German Basic Law, the embryo's right to life was not absolute, as according to the Basic Law it could be limited by law. Therefore, the Constitutional Court, while maintaining the definition of abortion as a crime, made it unpunishable if the woman would undergo counselling, and if her health condition would be affected by the embryo's pathologies. Thus, the Court made abortion possible, yet without abandoning the State's commitment to protecting human dignity.

In a rather similar way, the German Parliament allowed PGD. As a general rule, it recognised PGD as a crime. PGD was still regarded as a practice incompatible with the German *Sondermoral* and the principle of human dignity. However, by redefining the scope of subjects whose dignity the State must protect, the proponents of PGD managed to carve out a space

⁸³Bundesverfassungsgericht (BVerfGE), Urteil vom 28. Mai 1993, BVerfGE 88, 203.

for PGD in the German constitutional arrangements, to protect the interests of adult citizens alongside the interests of unborn life.

3.4. Conclusion

ART and embryo research, including hESC research, are problematised in Germany as a potential violation of the constitutional principle of human dignity, enshrined in art 1 of the German Basic Law. Whereas the Basic Law itself says nothing concerning the legitimacy of embryo manipulation and whether it violates human dignity, due to historical reasons, and mainly to the Nazi past of Germany, embryo research and experimentation were problematised as an assault on human dignity. Similarly, due to the memory of Nazi experiments, human dignity was conceptualised as the principle of non-instrumentalisation of human life. This implied that unborn life enjoyed strong protection in Germany. However, it was not absolute and did not entail an unrestricted right to life. This conceptualisation affected the way in which the EPA defined human life that the State was obliged to protect, that is, as human life from the moment of the fusion of the egg and the sperm and having the 'capacity to develop'.

The memory of the Nazi past was also the reason why there was a general consensus in German society about the need to prohibit embryo experimentation out of respect for human dignity. This general consensus underlay a speedy and rather unproblematic adoption of the EPA and a broad endorsement of its restrictive nature. Importantly, there was an agreement with respect to another value that also played an important role in the speedy passage of the Law and in its support. Of the utmost importance was the consent of women, needed to prevent forced medical treatments. Hence, the EPA already contained the two bioethical principles, dignity as constraint, underwriting the general prohibition of embryo experimentation, and dignity as empowerment, prohibiting forced IVF treatment and allowing women to withdraw their consent any time during the treatment. These two bioethical perspectives enjoyed wide societal support making the EPA almost entirely criticism-proof.

With the advent of new technologies, the extent to which the principle of human dignity encompassed embryo protection started to be questioned. The proponents of hESC research emphasised that the import of hESC from abroad would not violate human dignity if strong norms against such violation were embedded in the law and stressed another constitutional principle, the freedom of research. Similarly, the proponents of PGD emphasised the need to prevent negative impacts of raising children with severe genetic pathologies on women's lives, thereby invoking the dignity as empowerment principle. Importantly, the proponents of both technological advancements did not argue against the need to protect embryos from scientific experimentation

as such. At stake was the degree to which the competing interests and values could and should be taken into account.

The SCA that was eventually adopted together with the amendments to the EPA on PGD illustrate that a well-debated compromise was struck between the competing bioethical perspectives. Hence, the German regulator, while staying faithful to its constitutional values and historical memory, nevertheless approached and solved the problem of ‘regulatory connection’⁸⁴ and therefore stayed in touch with new techno-scientific realities, keeping them under its vigilant watch. In addition, by embracing different views on the ethical legitimacy of new technologies, it took into account different normative positions of its constituency.

4. Discussion and conclusion

The comparison between Italy and Germany provides a good illustration when the appeal to human dignity in public debates on new technologies involving the use of embryos becomes problematic. First, the appeal to human dignity raises significant controversy when dignitarianism does not constitute the main bioethical perspective in the country at stake. Specifically, the comparison of the policies of Italy and Germany showed differences in terms of their efficiency and durability exactly because of a different degree of support that this principle enjoyed in the two countries. Seeking not to repeat the horrors of Nazi Germany, German society broadly accepted that the regulation of new biomedical technologies must be in conformity with the principle of human dignity, conceptualised as the principle of non-instrumentalisation of human life. This enabled the speedy enactment of laws regulating ART and hESC research, which were seldom contested after their enactment. In contrast, in Italy, due to the secular/religious cleavage, only the religious part of Italian society fully supported the human dignity of embryos, conceptualised as sanctity of life. Moreover, the attempts of Italian politicians to embed this principle into law were rejected as inappropriate in a country where the Church is separated from the State. As a result, it led to a regulatory stalemate and underregulation of ART, both in the long period before the adoption of the Law on MAR and after the invalidation of the most restrictive provisions of the Law by the Constitutional Court. A similar underregulation also characterised the legal situation with hESC.

Second, the appeal to human dignity raises problems when the supporters of this principle may not be willing to compromise with their opponents. As has been demonstrated, the supporters of sanctity of life in Italy refused to seek out compromises with the supporters of more liberal views on ART

⁸⁴Brownsword (n 72).

and hESC research. In a country where this principle is not widely shared, the absolutism further exacerbated the controversy. In Germany, in contrast, the parties were open to compromises. Human dignity remained the main principle governing the development of policies. However, those who appealed to other principles such as freedom of research and dignity as empowerment also managed to have their position accommodated by law. Thus, 'human dignity as constraint' was combined with 'human dignity as empowerment' in the German policy on PGD. Although the outcome achieved by the German regulator may be criticised as incoherent, it had the advantage that it led to the closure of the controversy and the establishment of a tight and reliable mechanism of oversight on new technologies. In addition, through combining different perspectives, the German regulator undertook an attempt to stay in touch with techno-scientific realities and hence address the problem of 'regulatory connection'.⁸⁵ More importantly, such an outcome provided sufficient certainty for all the involved actors about their entitlements, duties and responsibilities.

While the focus of this paper is on human dignity, we suggest that its conclusions can be also indicative of general patterns of the relationships between particular bioethical configurations and countries' policies on new biomedical practices. In what follows, we will draw three broad patterns of how exactly bioethical configurations may shape regulatory policy. Clearly, in teasing out these patterns, we acknowledge that they do not work as uniform and rigid templates for how bioethical sensibilities of the relevant country shape its policy and therefore they must be applied with the utmost caution in further analysis. However, by drawing them we believe that they can make further research on this topic more analytically tractable and therefore act as useful methodological resources for other scholars exploring the connection between countries' bioethical landscapes and their regulatory policy.

The first pattern is the correspondence of the regulatory environment of a country with the country's dominant bioethical perspective. Put differently, if a specific bioethical perspective clearly dominates the bioethical landscape, the regulatory policy will reflect this perspective. Great Britain, where the utilitarian perspective is dominant, can exemplify this pattern. The second pattern is that in those countries where (a) several bioethical perspectives co-exist and (b) the supporters of competing perspectives are willing to make coalitions or strike compromises, the regulatory environment will reflect the terms of the compromise or coalition. We suggest that Germany might instantiate this principle. Although the 'dignity as constraint' principle remained the main regulatory principle, regulatory policy nevertheless accommodated 'the dignity as empowerment' perspective. Third, in countries where (a) several bioethical perspectives compete for regulatory relevance and

⁸⁵Ibid.

(b) their proponents are not willing to form coalitions or strike compromises, the regulatory outcome will be unpredictable and uncertain. We suggest that Italy followed this pattern; the reluctance of Catholic politicians to strike compromises with respect to the regulation of ART and hESC research led to significant periods of underregulation and legal uncertainty.

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